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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,010	11/22/2005	Chris Robert Lively	036481-0164	8892
22428 7590 09/06/2007 FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			EXAMINER KELLY, ROBERT M	
			ART UNIT 1633	PAPER NUMBER
			MAIL DATE 09/06/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/529,010

**Applicant(s)**

LIVELY ET AL.

**Examiner**

Robert M. Kelly

**Art Unit**

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) 8-11 and 47-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 12-46 and 67-71 is/are rejected.
- 7) ☒ Claim(s) 34-37 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/24/05; 2/28/06</u> | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant's response and amendment of 6/11/07 have been entered.

Claims 68-71 are newly added.

Claims 1-8, 12-48, and 67 are amended.

Claims 1-71 are presently pending.

### ***Election/Restrictions***

Applicant's election with traverse of Group I in the reply filed on 6/11/07 is acknowledged.

Applicant's amendment and argument to rejoin Groups II-IV and VII is persuasive, as the amendments appear to bring the claims within the scope of the same compositions.

Hence, Groups II-IV and VII are rejoined with the elected invention, Group I.

Claims 8-11 and 47-66 are withdrawn as being drawn to non-elected inventions.

### ***Claim Objections***

Claims 34-37 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The rejected claims encompass a broader scope of condensing polymer, which was amended to overcome the restriction requirement and bring the claims into the same invention, and hence, are objected-to for encompassing subject matter drawn to non-elected inventions.

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Hence, Claims 34-37 will be considered only for that subject encompassed by the elected invention: polyArginine polymers of 6-10 residues.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7, 12-13, 17-20, 22-30, 32-38, 42-45, and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,204,253 to Sanford, et al., and Balhorn, et al. (2000) Molecular Reproduction and Development, 56: 230-34, as evidenced by Oard (1993) Plant Cell, Tissue and Organ Culture, 33(3): 247-50.

With regard to Claims 1-3, 7, 13, 17-18, 25, 27, 28, 32-36, 38, 42-43 Sanford teaches M-10 series tungsten microprojectile particles (which range from 0.3 to 2.1 micrometers in diameter (e.g., Oard (1993) Plant Cell, Tissue and Organ Culture, 33(3): 247-50, p. 249, col. 1, paragraph 3), coated with DNA condensed in the presence of spermidine, and also in the presence of EDTA (e.g., col. 15, paragraph 2) and also in the presence of calcium chloride (e.g., Id.), and the methods of making claimed (e.g., Id.).

With regard to Claims 4-5, 28-29, Sanford teaches that a transgene for, *inter alia*, kanamycin resistance, is transformed into the cells, and further expressed (EXAMPLE 2). Kanamycin is a fungal protein, and hence, a Fungal antigen.

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With regard to Claims 19-20, 44-45, the particles are subsequently contacted with ethanol (e.g., col. 15, paragraph 3).

With regard to Claims 22-24, Sanford teaches a needleless syringe device, as it has no needle, but injects the particles into cells (e.g., Figure 1), and which contains a receptacle containing the particles for delivery (e.g., FIGURES 5a-5b).

With regard to Claim 26, Sanford teaches the addition of the spermidine to the mixture containing the microparticles and DNA (e.g., col. 15, paragraph 2).

However, with regard to all rejected claims, Sanford fails to teach the use of arginine of the formula  $[\text{Arg}]_{2-10}$  or a physiologically acceptable salt thereof.

However, the purpose of spermidine in condensing the DNA is to provide compact particles, resistant to degradation, as taught in the Art by Balhorn, et al. (2000) Molecular Reproduction and Development, 56: 230-34, e.g., p. 230, paragraph bridging columns. Further, Balhorn teaches that transformations of somatic cells and sperm are improved by the faster release of the DNA from condensation by the use of small polymers of polyArginine, and specifically, for the highest change in off-rate, those between 6-12 arginines having the greatest release kinetics (e.g., p. 233, paragraph bridging columns). Still further, Balhorn teaches that by simply changing the amount of arginines in the polyArginine in such delivery methods, the length of time required to dissociate from the polyArginine could be tailored for each individual delivery system (e.g., p. 233, column 2, paragraph 2).

Further, with regard to the presence of EDTA on the surface of the particle (e.g., Claim 67), absent reason to believe otherwise, these particles do have EDTA on their surface.

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Hence, at the time of invention, it would have been obvious to modify the microprojectile particles of Sanford with the use of the polyarginines of Balhorn, to arrive at the claimed invention. The Artisan would have been motivated to do so to arrive at the desired release kinetics for any specific system. Moreover, the Artisan would have had a reasonable expectation of success, as Balhorn had already demonstrated the release kinetics to be improved.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7, 12-15, 17-30, 32-40, 42-46, and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,204,253 to Sanford, et al., and Balhorn, et al. (2000) Molecular Reproduction and Development, 56: 230-34, as evidenced by Oard (1993) Plant Cell, Tissue and Organ Culture, 33(3): 247-50, as applied to claims 1-5, 7, 12-13, 17-20, 22-30, 32-38, 42-45, and 67, above, and further in view of Oard (1993) Plant Cell, Tissue, and Organ Culture, 33(3): 247-50 and Cherng, et al. (1999) Pharmaceutical Research, 16(9): 1417-23.

With regard to Claims 1-5, 7, 12-13, 17-20, 22-30, 32-38, 42-45, and 67, as is shown above, Sanford and Balhorn, as further evidenced by Oard, make obvious the various aspects of the claims.

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However, Sanford and Balhorn, as further evidenced by Oard, do not make obvious the use of gold particles, further condensed in the presence of sucrose.

On the other hand, Oard teaches the use of gold particles can reduce particle clumping (e.g., p. 249, paragraph bridging columns). Further, Cherng teaches that condensation of nucleic acids with cationic polymers is further stabilized for storage by the presence of sucrose during the condensation (e.g., ABSTRACT).

Hence, at the time of invention, it would have been obvious to modify the techniques of Sanford and Balhorn, as further evidenced by Oard, to use the gold particles of Oard to reduce clumping, and further to condense the DNA in the presence of sucrose as taught by Cherng, to increase the stability of the condensed DNA over time. Moreover, the Artisan would have had a reasonable expectation of success, as Oard teaches that gold particles will reduce clumping and Cherng taught that the sucrose present in the condensed solution would provide more stability.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 12-46, and 67-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over .S. Patent No. 5,204,253 to Sanford, et al., and Balhorn, et al. (2000) Molecular Reproduction and Development, 56: 230-34, as evidenced by Oard (1993) Plant Cell, Tissue and Organ Culture, 33(3): 247-50, and further in view of Oard (1993) Plant Cell, Tissue, and Organ

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Culture, 33(3): 247-50 and Cherng, et al. (1999) Pharmaceutical Research, 16(9): 1417-23, as applied to claims 1-5, 7, 12-15, 17-30, 32-40, 42-46, and 67 above, and further in view of U.S. Patent Publication No. 2004/0142475 to Barman, et al.

As shown above, Claims 1-5, 7, 12-15, 17-30, 32-40, 42-46, and 67 are obvious over the Art cited, except the cited Art does not specifically teach the use of transgenes encoding therapeutic proteins, or the use of a combination of raffinose and sucrose to stabilize the DNA. Nor does the cited art teach or make obvious the transgenes encoding HPV, HIV, HSV2, HSV1 or Hepatitis B antigens.

On the other hand, Barman teaches that stabilizers such as saccharides may be used in combination to stabilize the nucleic acid protein complexes (e.g., paragraph 0052). Further, Barman teaches that HPV, HIV, HBV, and HSV (which includes HSV1 and HSV 2), antigens can be the transgenes for expression of antigens (paragraph 0036).

Hence, at the time of invention, it would have been obvious to modify the cited Art with Barman to use both raffinose and sucrose in stabilizing the particles and/or to use the various cited virus proteins. The Artisan would have been motivated to do so as the art already recognized that the sugars could be used in combination and/or the various proteins could be expressed for making antigens. Moreover, the Artisan would have had a reasonable expectation of success, as the Art already recognized the efficacious effect of saccharides.

### ***Conclusion***

No Claim is allowed.



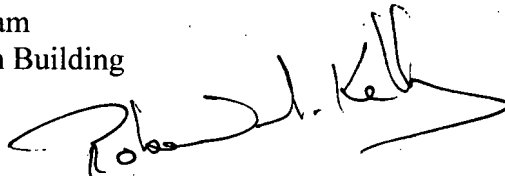
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Kelly, Art Unit 1633, whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read "Robert M. Kelly", with a stylized flourish at the end.